



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1794]

Agency Information Collection Activities; Proposed Collection; Comment Request; Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-To-Consumer Prescription Drug Ads

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, “Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in DTC Prescription Drug Ads.” This project will examine the effects of variation in ad exposure frequency on perception and mental processing of risk and benefit information in direct-to-consumer (DTC) prescription drug ads.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit

Information in DTC Prescription Drug Ads--(OMB Control Number 0910-NEW)

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

In a typical promotional campaign, consumers may be exposed to a DTC prescription drug ad any number of times. Perceptual and cognitive effects of increased ad exposure frequency have been studied extensively using non-drug ads. For instance, one study demonstrated that a commercial message repeated twice generates better recall than a message broadcast only once (Ref. 1). Another study demonstrated that increased ad exposures improve product attitudes and recall for product attributes, particularly when the substance of the repeat messages is varied (Ref. 2). Generally, it has been argued that first exposure to an ad results in attention, second exposure affects learning of the advertised message, and third and subsequent exposures reinforce the learning effects of the second exposure (Ref. 3). To our knowledge, the literature concerning ad exposure frequency has not been extended to include specific attention to prescription drug ads. Prescription drug ads are unique in that they are required to provide both benefit and risk information whereas other ad types tend to include only benefit information. The Office of Prescription Drug Promotion plans to examine the effects of

variation in ad exposure frequency on perception and mental processing of risk and benefit information in DTC prescription drug ads through empirical research.

The main study will be preceded by up to two pretests designed to delineate the procedures and measures used in the main study. Across pretests and the main study, participants will be individuals who have been diagnosed with seasonal allergies. All participants will be 18 years of age or older. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Participants will be recruited in one of two geographic locations (Washington, D.C. and Raleigh-Durham, NC) for in-person administration of protocols.

The experimental design is summarized in Table 1. Participants will be randomly assigned to view a prescription drug ad one, three, or six times as part of clutter reels embedded in a 42 minute TV program. They will then answer preprogrammed survey questions on laptops. Preliminary measures are designed to assess perception, memory, judgments about the ad, intentions to use the medication advertised, and possible moderators of effects, such as need for cognition and demographics. The questionnaire is available upon request. Participation is estimated to take up to 2 hours.

Table 1.--Experimental Design

Experimental Arm No.	42 Minute Television Show, Clutter Reel No.					
	1	2	3	4	5	6
1 (views ad 1 time)						Mock DTC ad
2 (views ad 3 times)	Mock DTC ad			Mock DTC ad		Mock DTC ad
3 (views ad 6 times)	Mock DTC ad	Mock DTC ad	Mock DTC ad	Mock DTC ad	Mock DTC ad	Mock DTC ad

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described in the following table, we will have sufficient power to detect small-to-medium sized effects in the main study.

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Average Burden per Response	Total Hours
Pretest 1 screener completes (assumes 10% eligible)	4,150	1	4,150	0.08 (5 minutes)	332
Pretest 2 screener completes (assumes 10% eligible)	4,150	1	4,150	0.08 (5 minutes)	332
Number of main study screener completes (assumes 10% eligible)	620	1	620	0.08 (5 minutes)	50
Pretest 1 completes	420	1	420	2	840
Pretest 2 completes	420	1	420	2	840
Number of completes, main study	620	1	620	2	1240
Total					3,634

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Singh, S. N., D. Linville, and A. Sukhdial, "Enhancing the Efficacy of Split Thirty-Second Television Commercials: An Encoding Variability Application," Journal of Advertising, 24, pp. 13-23 (1995).

2. Haugtvedt, C. P., et al., "Advertising Repetition and Variation Strategies: Implications for Understanding Attitude Strength," Journal of Consumer Research, 21, pp. 176-189 (1994).

3. Naples, M. J., "Effective Frequency: Then and Now," Journal of Advertising Research, 37, pp. 7-12 (1997).

Dated: November 5, 2014.

Leslie Kux,

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